K113279

NOV 14 2011

510(K) Summary

A. Submitter Information

Submitter's Name:	Kettenbach GmbH & Co. KG
Address:	Im Heerfeld 7 D-35713 Eschenburg, Germany
Phone Number:	(+49) 2774-705-58
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Contact Person:	Simone Matuschka
Date of Preparation:	August 1st, 2011

B. Device Name

Trade Name: *Identium® Impression Materials*, to include:

- *Identium® Heavy (regular – and fast-set in 1:1 cartridge system)*
- *Identium® Medium (regular – and fast- set in 1:1 cartridge system)*
- *Identium® Scan Heavy (regular-set in 1:5 foil bag)*
- *Identium® Scan Medium (regular-set in 1:5 foil bag)*
- *Identium® Scan Light (regular-set in 1:1 cartridge)*

Common/Usual Name: Impression Material

Classification Name: Material, Impression (21 CFR 872.3660, Product Code: ELW)

C. Predicate Devices

Trade Name:

- *Identium® Impression Materials* (K092867) including:
  Identium® Heavy (regular and fast set in 1:5 foil bag)
  Identium® Medium (regular and fast set in 1:5 foil bag system),
  Identium® Light (regular and fast set in 1:5 foil bag system)
- *Panasil® monophase (regular, 1:1 cartidge)* - (K082560)
- *Futar® Scan (1:1 cartridge) - (K081120)*

D. Device Description

Identium® Impression Materials are addition-curing, elastomeric materials. *Identium® Impression Materials* have excellent flow and hydrophilic properties, high shear strength, dimensional accuracy and resistance to permanent deformation. The *Identium® Impression Materials* include three different viscosities (heavy-bodied, medium-bodied, light-bodied), available in an assortment of delivery systems:
Traditional 1:1 50 ml automix cartridge version and 5:1 362 ml foil bags for use in most automatic dispensing and mixing systems (heavy-bodied and medium-bodied versions only). Most of the *Identium® Impression Materials* are available in a regular-set and a fast-set version.

E. Intended Use

The *Identium® Impression Materials* are intended to:

- be placed on an impression tray (or injected directly into the mouth, depending on the technique and device) and used to reproduce the structure of a patient's teeth and gums;
- provide models for study and for production of restorative prosthetic devices.

Indications for Use:

Heavy - bodied Identium® Impression Materials (fast- and regular set) are to be used for:

- Impressions for crowns/bridges, inlays/onlays and veneer preparations
- Functional impressions
- Impressions for full or partial dentures
- Implant impressions

Medium - bodied Identium® Impression Materials (fast- and regular set) are to be used for:

- Impressions for crowns/bridges, inlays/onlays and veneer preparations
- Functional impressions
- Fixation impressions
- Implant impressions

Ligtht - bodied Identium® Impression Materials (fast- and regular set) are to be used for:

- Impressions for crowns/bridges, inlays/onlays and veneer preparations
- Reline impressions
- Impressions for full or partial dentures

F. Technological Characteristics Summary

The technological characteristics of the *Identium® Impression Material* subject devices *Identium® Heavy (in 1:1 cartridge), Identium® Medium(in 1:1 cartridge) Identium® Scan Heavy, Identium® Scan Medium* and *Identium® Scan Light* are substantially equivalent to the *Identium®, Panasil® and Futar®Scan Impression Material* predicate devices' technological characteristics. The subject devices and the predicate devices are addition-curing, elastomeric materials, designed and manufactured for use as dental impression materials *(product code ELW)*.

G. Performance Data

No performance standards have been established for this type of device. *Identium® Impression Material* subject devices *(Identium® Heavy and Identium® Medium* in 1:1 cartridges, *Identium® Scan Heavy , Identium® Scan Medium and Identium® Scan Light*) have been evaluated in accordance with the applicable criteria established in *Guidance for Industry and FDA Staff: Dental Impression Materials – Premarket Notification (FOD#2203, 8/17/1998)* and *ISO 4823 (Dentistry – Elastomeric impression materials):2000/Cor 1:2004/Amd 1:2007*. The results of performance testing demonstrated that *Identium® Impression Material* subject devices *(Identium® Heavy and Identium® Medium* in 1:1 cartridges, *Identium® Scan Heavy , Identium® Scan Medium and Identium® Scan Light*) are suitable for use as dental impression materials. *Identium® Impression Material* subject devices*(Identium® Heavy and Identium® Medium* in 1:1 cartridges, *Identium® Scan Heavy , Identium® Scan Medium and Identium® Scan Light*) have been designed and manufactured to perform in a manner substantially equivalent to that of the predicate devices.

H. Clinical Tests

Clinical testing has not been conducted on the subject devives.

I. Conclusion

Based upon the similar intended use, the performance data according to ISO 4823, the evaluation/justification of the biocompatibility and the risk analysis acc. ISO 14971 the subject devices *(Identium® Heavy and Identium® Medium* in 1:1 cartridges, *Identium® Scan Heavy , Identium® Scan Medium and Identium® Scan Light*) are substantially equivalent to the predicate devices and can be considered to be as safe, as effective and performs as well as or better than the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

NOV 14 2011

Kettenbach GmbH & Co. KG
C/O Mr. Norbert Stuiber
TUV SUD America, Inc.
1775 Old Highway 8, NW
New Brighton, MN 55112-1891

Re: K113279
Trade/Device Names: Identium® Impression Materials (Heavy, Medium, Scan Heavy, Scan Medium, and Scan Light)
Regulation Number: 21 CFR 872.3660
Regulation Name: Impression Material
Regulatory Class: II
Product Code: ELW
Dated: November 3, 2011
Received: November 7, 2011

Dear Mr. Stuiber:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113279

Device Name:

Identium® Heavy

Indications For Use:

Identium® Heavy (regular 1:1, fast 1:1) is to be used as a heavy-bodied impression material in one-step technique (double mix) for:

- Impressions for crowns/bridges, inlays/onlays and veneer preparations
- Functional impressions
- Impressions for full or partial dentures
- Implant impressions

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K113279

Indications for Use

510(k) Number (if known): K113279

Device Name:

Identium® Medium

Indications For Use:

Identium® Medium (regular 1:1, fast 1:1) is to be used as a medium-bodied tray or syringeable impression material in one-step technique (monophase or double mix) for:

- Impressions for crowns/bridges, inlays/onlays and veneer preparations
- Functional impressions
- Fixation impressions
- Implant impressions

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C

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Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K113279

Indications for Use

510(k) Number (if known): K113279

Device Name:

Identium® Scan Heavy

Indications For Use:

Identium® Scan Heavy (regular 1:5) is to be used as a heavy-bodied impression material in one-step technique (double mix) for:

- Impressions for crowns/bridges, inlays/onlays and veneer preparations
- Functional impressions
- Impressions for full or partial dentures
- Implant impressions

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C

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510(k) Number: K113279

Indications for Use

510(k) Number (if known): K113279

Device Name:

Identium® Scan Medium

Indications For Use:

Identium® Scan Medium (regular 1:5) is to be used as a medium-bodied tray or syringeable impression material in one-step technique (monophase or double mix) for:

- Impressions for crowns/bridges, inlays/onlays and veneer preparations
- Functional impressions
- Fixation impressions
- Implant impressions

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C

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Infection Control, Dental Devices

510(k) Number: K113279

Indications for Use

510(k) Number (if known): K113279

Device Name:

Identium® Scan Light

Indications For Use:

Identium® Scan Light (regular 1:1) is to be used as a syringeable light-bodied impression material in one-step technique (double mix) for:

- Impressions for crowns/bridges, inlays/onlays and veneer preparations
- Reline impressions
- Impressions for full or partial dentures

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C

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